

**APPENDIX B --COPY OF INFORMATION DISCLOSURE STATEMENT FILED
ON MARCH 9, 2000 WITH COPY OF POST CARD RECEIPT**





Applicants: Chu *et al.*

Application No.: 09/438,365

Filed: November 12, 1999

For: **New Transfection Reagents**

Due Date:

Art Unit: To be assigned

Examiner: To be assigned

Docket: 0942.4650001

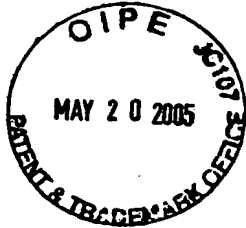
Atty: RWE/THN

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. PTO Transmittal Letter (*in duplicate*);
2. Information Disclosure Statement (*in duplicate*);
3. Form PTO-1449 (5 sheets citing 51 documents); and
4. 51 documents cited in Form PTO-1449.



Please Date Stamp And Return To Our Courier



STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

ATTORNEYS AT LAW

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(202) 371-2600

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FILE COPY

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SUZANNE E. ZISKA**
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ANDREA J. KAMAGE**
NANCY J. LEITH**
TARJA H. NAUKKARINEN**

*BAR OTHER THAN D.C.
**REGISTERED PATENT AGENTS

March 9, 2000

WRITER'S DIRECT NUMBER:
(202) 371-2560

INTERNET ADDRESS:
RESMOND@SKGF.COM

Assistant Commissioner for Patents
Washington, D.C. 20231

Re: U.S. Utility Patent Appl. No. 09/438,365; Filed: November 12, 1999
For: **New Transfection Reagents**
Inventors: Chu *et al.*
Our Ref: 0942.4650001/RWE/THN

Sir:

Applicants submit the following documents for appropriate action by the U.S. Patent and Trademark Office:

1. Information Disclosure Statement (*in duplicate*);
2. Form PTO-1449 (5 sheets citing 51 documents);
3. 51 documents cited in Form PTO-1449; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Assistant Commissioner for Patents

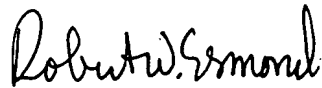
March 9, 2000

Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge all requisite fees to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

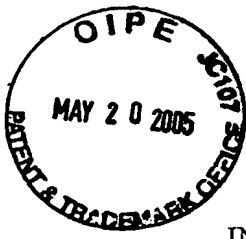
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Robert W. Esmond". The signature is written in a cursive, flowing style.

Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

RWE/THN/lam

Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Chu *et al.*

Appl. No. 09/438,365

Filed: November 12, 1999

For: New Transfection Reagents

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 0942.4650001/RWE/THN

Information Disclosure Statement

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

The Examiner's attention is directed to co-pending U.S. Patent Application Nos. 08/450,555 filed May 25, 1995 and 09/039,780 filed March 16, 1998, which are directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language document, Document No. AL1, cited on Form PTO-1449.

Document No. AL1, European Patent No. EP 0 394 111 B1, is in French. It is believed to disclose lipopolyamines, which are especially useful as vectors for the transfection of eukaryotic

cells, their salts, their preparation and their use. Document No. AE1, U.S. Patent No. 5,171,678, is believed to be an English language equivalent of Document No. A11.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

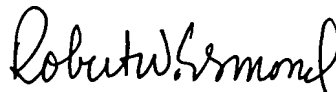
It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date but before the mailing date of a first Office Action on the merits.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

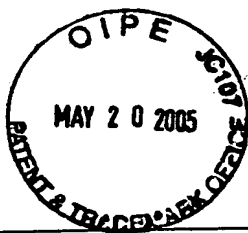
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: March 9, 2000

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
0942.4650001

APPLICATION NO.
09/438,365

APPLICANT
Chu *et al.*

FILING DATE
November 12, 1999

GROUP
To be assigned

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|---------------------|-----|-----------------|------------|------------------------|-------|-----------|-------------|
| | AA1 | 2,695,314 | 11/23/1954 | Kosmin, M. | 260 | 584 | 08/25/1951 |
| | AB1 | 2,901,461 | 08/25/1959 | Auerbach <i>et al.</i> | 260 | 47 | 05/05/1955 |
| | AC1 | 3,152,188 | 10/06/1964 | Kirkpatrick, W.H. | 260 | 584 | 11/15/1960 |
| | AD1 | 4,897,355 | 01/30/1990 | Eppstein <i>et al.</i> | 435 | 240.2 | 10/29/1987 |
| | AE1 | 5,171,678 | 12/15/1992 | Behr <i>et al.</i> | 435 | 172.3 | 04/17/1990 |
| | AF1 | 5,208,036 | 05/04/1993 | Eppstein <i>et al.</i> | 424 | 450 | 11/16/1990 |
| | AG1 | 5,279,833 | 01/18/1994 | Rose, J.K. | 424 | 450 | 04/04/1990 |
| | AH1 | 5,283,185 | 02/01/1994 | Epand <i>et al.</i> | 435 | 172.3 | 08/28/1991 |
| | AI1 | 5,334,761 | 08/02/1994 | Gebeyehu <i>et al.</i> | 564 | 197 | 08/28/1992 |
| | AJ1 | 5,455,335 | 10/03/1995 | Kahne <i>et al.</i> | 536 | 5 | 04/08/1994 |
| | AK1 | 5,459,127 | 10/17/1995 | Felgner <i>et al.</i> | 514 | 7 | 09/16/1993 |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|---------------------|-----|-----------------|------------|---------|-------|-----------|-------------|
| | AL1 | EP 0 394 111 B1 | 06/04/1997 | Europe | | | Yes No |
| | AM1 | WO 94/27435 A1 | 12/08/1994 | WIPO | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

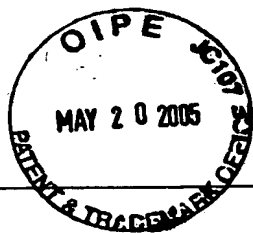
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| AR | 1 | Bangham, A.D. <i>et al.</i> , "Diffusion of Univalent Ions across the Lamellae of Swollen Phospholipids," <i>J. Mol. Biol.</i> 13:238-252 (1965). |
| AS | 1 | Behr, J.-P. <i>et al.</i> , "Efficient gene transfer into mammalian primary endocrine cells with lipopolyamine-coated DNA," <i>Proc. Natl. Acad. Sci. USA</i> 86:6982-6986 (September 1989). |
| AT | 1 | Felgner, P.L. <i>et al.</i> , "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417 (November 1987). |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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|---------------------|-----|-----------------|------------|----------------------|-------|-----------|-------------|
| | AA2 | 5,545,412 | 08/13/1996 | Eppstein et al. | 424 | 450 | 04/03/1995 |
| | AB2 | 5,550,289 | 08/27/1996 | Eppstein et al. | 564 | 293 | 04/03/1995 |
| | AC2 | 5,589,466 | 12/31/1996 | Felgner et al. | 514 | 44 | 01/26/1995 |
| | AD2 | 5,667,774 | 09/16/1997 | Figuly, G.D. | 424 | 78.08 | 11/07/1996 |
| | AE2 | 5,674,908 | 10/07/1997 | Haces et al. | 514 | 642 | 12/20/1993 |
| | AF2 | 5,703,055 | 12/30/1997 | Felgner et al. | 514 | 44 | 01/26/1994 |
| | AG2 | 5,705,385 | 01/06/1998 | Bally et al. | 435 | 320.1 | 06/07/1995 |
| | AH2 | 5,719,131 | 02/17/1998 | Harris et al. | 514 | 44 | 10/20/1995 |
| | AI2 | 5,736,392 | 04/07/1998 | Hawley-Nelson et al. | 435 | 320.1 | 06/04/1996 |
| | AJ2 | 5,753,613 | 05/19/1998 | Ansell et al. | 514 | 2 | 05/16/1995 |
| | AK2 | 5,783,565 | 07/21/1998 | Lee et al. | 514 | 44 | 02/01/1996 |

FOREIGN PATENT DOCUMENTS

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|---------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

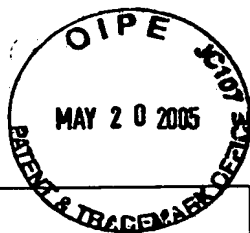
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|---|--|
| | AR | 2 | Fukunaga, M. et al., "Liposome Entrapment Enhances the Hypocalcemic Action of Parenterally Administered Calcitonin," <i>Endocrinol.</i> 115:757-761 (1984). |
| | AS | 2 | Gao, X. and Huang, L., "A Novel Cationic Liposome Reagent for Efficient Transfection of Mammalian Cells," <i>Biochem. Biophys. Res. Comm.</i> 179:280-285 (August 1991). |
| | AT | 2 | Hart, S.L. et al., "Lipid-Mediated Enhancement of Transfection by a Nonviral Integrin-Targeting Vector," <i>Hum. Gene Ther.</i> 9:575-585 (March 1998). |

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|---------------------|-----|-----------------|------------|-------------------------|-------|-----------|-------------|
| | AA3 | 5,783,566 | 07/21/1998 | Mislick, K.A. | 514 | 44 | 05/10/1996 |
| | AB3 | 5,785,992 | 07/28/1998 | Ansell <i>et al.</i> | 424 | 450 | 09/29/1995 |
| | AC3 | 5,795,587 | 08/18/1998 | Gao <i>et al.</i> | 424 | 450 | 01/23/1995 |
| | AD3 | 5,830,430 | 11/03/1998 | Unger <i>et al.</i> | 424 | 1.21 | 02/21/1995 |
| | AE3 | 5,830,878 | 11/03/1998 | Gorman <i>et al.</i> | 514 | 44 | 06/07/1995 |
| | AF3 | 5,834,439 | 11/10/1998 | Haces <i>et al.</i> | 514 | 42 | 01/13/1997 |
| | AG3 | 5,837,283 | 11/17/1998 | McDonald <i>et al.</i> | 424 | 450 | 03/12/1997 |
| | AH3 | 5,840,710 | 11/24/1998 | Lee <i>et al.</i> | 514 | 44 | 10/20/1995 |
| | AI3 | 5,908,635 | 06/01/1999 | Thierry, A. | 424 | 450 | 08/05/1994 |
| | AJ3 | 5,935,936 | 08/10/1999 | Fasbender <i>et al.</i> | 514 | 44 | 06/03/1996 |
| | AK3 | 5,948,925 | 09/07/1999 | Keynes <i>et al.</i> | 552 | 540 | 05/06/1997 |

FOREIGN PATENT DOCUMENTS

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|---------------------|----|-----------------|------|---------|-------|-----------|-------------|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
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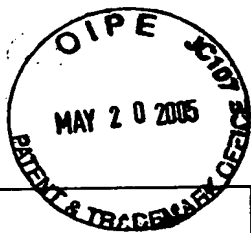
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|---|---|
| | AR | 3 | Kim, S. <i>et al.</i> , "Preparation of Multivesicular Liposomes," <i>Biochim. Biophys. Acta</i> 728:339-348 (1983). |
| | AS | 3 | Mayer, L.D. <i>et al.</i> , "Vesicles of variable sizes produced by a rapid extrusion procedure," <i>Biochim. Biophys. Acta</i> 858:161-168 (1986). |
| | AT | 3 | Mayhew, E. <i>et al.</i> , "Characterization of Liposomes Prepared Using a Microemulsifier," <i>Biochim. Biophys. Acta</i> 775:169-174 (1984). |

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|---------------------|-----|-----------------|------------|---------------------|-------|-----------|-------------|
| | AA4 | 5,948,767 | 09/07/1999 | Scheule et al. | 514 | 44 | 07/12/1996 |
| | AB4 | 5,962,533 | 10/05/1999 | Bergeron, Jr., R.J. | 514 | 674 | 02/06/1996 |
| | AC | | | | | | |
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| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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|--|----|---|---|
| | AR | 4 | Olson, F. et al., "Preparation of Liposomes of Defined Size Distribution by Extrusion Through Polycarbonate Membranes," <i>Biochim. Biophys. Acta</i> 557:9-23 (1979). |
| | AS | 4 | Rosenthal, A.F. and Geyer, R.P., "A Synthetic Inhibitor of Venom Lecithinase A," <i>J. Biol. Chem.</i> 235:2202-2206 (August 1960). |
| | AT | 4 | Szoka Jr., F. and Papahadjopoulos, D., "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Natl. Acad. Sci. USA</i> 75:4194-4198 (1978). |

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| | AA | | | | | | |
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| | AL | | | | | | Yes No |
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| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | |
|--|----|----------|--|
| | AR | <u>5</u> | Zhou, X. <i>et al.</i> , "Lipophilic polylysines mediate efficient DNA transfection in mammalian cells," <i>Biochim. Biophys. Acta</i> 1065:8-14 (1991). |
| | AS | <u>5</u> | Life Technologies Inc. catalogue, <i>Spectrum</i> , pp. 1-8 (September 1999). |
| | AT | | |

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